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TAGS: [ETRD](#) [KS](#)
SUBJECT: PHARMACEUTICALS AND KORUS-FTA: TURNING THE TABLES

REF: A. SEOUL 2421
[1](#)B. STATE 116991
[1](#)C. SEOUL 2210

Classified By: Ambassador Alexander Vershbow. Reasons 1.4 (B,D & E)

[1](#)1. (C) SUMMARY: With public release of the draft implementing regulations for its Drug Expenditure Rationalization Plan (DERP) scheduled for July 26, the ROKG has slowly but steadily backed away from all the key commitments it made to us on treatment of pharmaceuticals in the FTA, and has now withdrawn its commitment to negotiate the terms of the new "positive list" system in the FTA Pharmaceuticals Working Group (ref a). The 60-day comment period on the regs will start as of their public release July 26, as promised; but the ROKG currently envisages this public comment period as ROKG-industry discussions, while characterizing any discussion within the FTA Pharma WG as an information exchange, rather than a negotiation. The proposed pharma regs are a prime example of the kind of regulatory non-transparency that we have been seeking to reduce through the FTA, as non-tariff barriers (NTBs) restricting market access. Because the ROKG's handling of the pharma issue in the FTA thus far raises concerns beyond this particular working group, post recommends a tough but graduated response: (1) to reject the ROKG's refusal to negotiate as unacceptable; (2) to insist on negotiations on the terms for authorization and reimbursement of pharmaceuticals under a positive list system; (3) to demand an extraordinary session of the FTA Pharmaceuticals Working Group in mid-to-late August, where the U.S. will present a comprehensive proposal; and (4) to postpone the Third Round of FTA talks if the ROKG refuses to negotiate in good faith. Details at para 11. END SUMMARY.

THE BACKGROUND: THE ROKG RENEGES

[1](#)2. (SBU) As previewed in ref a discussions, on Monday July 24 at 1900 local (0600 Washington time), MOFAT sent draft implementing regulations for the Drug Expenditure Rationalization Plan (DERP) via AmEmbassy Seoul and the Korean Embassy in Washington for transmittal to USG and U.S. interested parties. The 26-page draft was provided in Korean only. MOFAT did transmit two related English-language explanations of the proposed regulatory changes, and industry provided an English translation of the draft regs within 12 hours. However, regarding the original parameters for delivery of the documents as discussed with the ROKG (ref a), MHW plans to release the draft implementing regs Wednesday July 26, limiting the U.S. side's time to review and comment on the documents to one working day prior to release.

Further, MOFAT conveyed that the 60-day official public comment period within Korea would start as of July 26, but that any discussion of the draft implementing regs in the FTA Pharmaceuticals and Medical Devices Working Group would be an information exchange, not negotiation of the details of the implementing regs. Embassy learned that MHW briefed the Korean press on the draft implementing regs on July 24, while embargoing the news until their official release July 26. As usual, the press embargo was not respected, and the story was out by mid-day July 25.

13. (SBU) In July 24 meetings at the Blue House and with the ROK's chief FTA negotiator, the Ambassador and visiting Commerce U/S Frank Lavin pressed the case that the ROKG had promised us an opportunity for meaningful review of and comment on the draft implementing regs prior to their public release, as well as an opportunity to negotiate on the substance of the regs in the context of the FTA Pharmaceuticals/Medical Devices Working Group. At the time the pharma WG talks were suspended during the FTA negotiations in Seoul two weeks ago, the USG offered to accept the positive list as a concept, in exchange for transparency in and dialogue on implementing the new approach. It now appeared that the ROKG was backtracking on those commitments, the Ambassador and U/S Lavin made clear, and the USG would have to consider its response to these negative developments.

14. (SBU) In response to the above, Blue House Senior Secretary for Economic Affairs Yoon Dae-hee confirmed that

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discussions within the ROKG on the draft implementing regs had continued throughout the weekend. But he admitted that one of the outcomes was that exchanges in the FTA Pharma/Med Devices WG would be information exchanges, not negotiations of the details of the regs. Yoon pointed to Deputy PM/Finance Minister Kwon O-kyu as the Cabinet official coordinating the ROKG position on the release of the draft regs.

15. (SBU) ROK chief FTA negotiator Kim Jong-hoon expressed his discouragement with the outcome of ROKG interagency discussions, saying the things were not working out in the direction he and Trade Minister Kim Hyun-chong had desired. However, rather than focus on the procedural aspects of whether the ROKG had abided by its commitments, first for a standstill, then for transparency and dialogue, he instead repeated the ROKG's earlier request (ref c) that the U.S. side spell out its real problems with the substance of the positive list proposal. He said he had never really understood what our issues were with the proposal itself, and further assured the Ambassador and U/S Lavin that the DERP would be non-discriminatory and scientifically-based.

16. (C) Following the Yoon and Kim Jong-hoon meetings, Trade Minister Kim Hyun-chong phoned the Ambassador in the afternoon of July 24. Kim said he had been "fighting like hell" on behalf of the parameters for release of the draft implementing regs to which the ROKG had committed (i.e., sharing them pre-release with the USG, allowing time for meaningful comment prior to their public release, starting the 60-day public comment period only with their release, and providing an opportunity for negotiation within the FTA Pharma/Med Devices WG). Kim said that the July 21 Blue House meeting that discussed the process for releasing the draft regs had focused on the strongly adverse public reaction to press stories claiming that the ROKG had caved prior to the start of FTA talks by agreeing to the "four preconditions" (on autos, beef, pharma, and screen quotas). An MBC TV program last week showed a USG official citing these four, Kim said, and this put the advocates of an FTA -- and him personally -- under pressure.

17. (C) Minister Kim asked what Washington was likely to do. The Ambassador said the situation was very serious, and that if things came out the way they were heading on the ROKG side, there was no guarantee the FTA talks would be able to

resume as scheduled in September. In the best case, he said, the USG might follow the approach described by Graham Allison in his book on the Cuban missile crisis, i.e. to respond not to the last message received, if unacceptable, but to the one before that -- i.e. to simply insist that the terms of the new system be negotiated in the FTA talks. Kim said he had read Allison's book and understood the point. If things were to go badly when the ROKG did pre-release the draft, he would understand if the USG suspended either the Pharma/Med Devices WG, or suspended the FTA talks altogether, but he hoped things wouldn't come to that.

18. (C) The Ambassador said that the negative developments might lead some in the USG to wonder whether the Blue House was playing a cynical game, professing publicly to want an FTA, but in reality getting cold feet and starting to back away, using the new pharmaceutical system as a means to shift the blame to the U.S. Minister Kim, speaking on an open line, said that President Roh Moo-hyun still wants the FTA. The Ambassador said we did not doubt the ROK President's commitment but, at a minimum, President Roh does not appear to be in control of all his ministers. Again, Minister Kim demurred, saying he couldn't confirm that, but he could understand how the Ambassador might have that impression.

RESTORING THE BASIS FOR NEGOTIATIONS

19. (C) Looking back over the past seven-eight months, it is undeniable that the Koreans have walked back virtually every commitment on pharmaceuticals, beginning with the promised "standstill" on changes to the pharma reimbursement system during the negotiations. That being said, there are reasons to avoid overreacting:

-- Starting with the optics, no politician wants to be seen helping "big pharma." Further, even the USG has acknowledged that health care reform is a Korean prerogative and that the current reimbursement system needs change;

-- Second, playing up the "bad faith" argument that the ROKG did not abide by the commitments it made as a precondition to FTA talks is likely to play into the hands of FTA opponents. The Blue House has had to respond publicly to allegations that Korea caved on key issues in order to launch FTA talks.

110. (C) At the same time, there are also reasons to avoid underreacting to what has happened. Backward movement of this kind, in the direction of arbitrary and non-transparent regulation, lessens the hope that an FTA can get at the non-tariff barriers that figure so centrally in our trade problems with the ROK. Procedurally, the ROKG has played bait-and-switch on the pharmaceuticals issue. If we stand for this in pharmaceuticals, they may feel they can try the same tactics in other areas. Meanwhile, a key U.S. constituency for the FTA will have turned against the agreement, likely precipitating its rejection by Congress.

111. (C) Post therefore recommends Washington consider a tough but graduated approach.

-- First, declare that the ROKG's handling of a major change to its pharmaceuticals reimbursement system, without meaningful discussion in the FTA context, is unacceptable. The ROKG knew this issue to be of major concern to us, yet they moved the goalposts repeatedly before real negotiations began.

-- Second, make clear that the USG insists/insists on negotiations in the FTA context and intends to hold the ROKG to the commitments it made previously, before this week's walk-back.

-- On this basis, the USG will prepare a proposal spelling out the detailed USG and U.S. industry concerns with the DERP, for an extraordinary meeting of the FTA Pharma and Med Devices WG during the third or fourth week of August. The U.S. can accept a positive list approach, but it needs to be done right.

-- Finally, if Korea refuses to negotiate, the third negotiating round will be postponed indefinitely. At their September summit meeting, President Bush and President Roh can then discuss the future of the talks.

¶12. (C) We do not rate the odds of an ROKG climbdown as high, but we believe we should give them one last chance to reconsider before taking the dramatic step of canceling the September FTA round. We would emphasize to Washington the importance of coming up with a comprehensive U.S. negotiating position for the extraordinary session of the working group. The Koreans will not alter their present course unless we present a clear and reasonable alternative that shows them they can still have reform and satisfy our concerns in the FTA. You can't fight something with nothing.

¶13. (C) We look forward to Washington's reaction and guidance.

VERSHBOW